



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	342615	INNER HEALTH ECZEMA SHIELD KIDS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	31/08/2020	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . INNER HEALTH ECZEMA SHIELD KIDS

Product Type	Single Medicine Product	Effective Date	31/08/2020
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Helps reduce occurrence of symptoms of mild allergies in children
Maintain/support healthy immune system function in children
Decrease/reduce/relieve itchy/prickling skin associated with mild eczema/dermatitis when sun exposure is inadequate in children
Decrease/reduce/relieve symptoms of mild eczema/dermatitis when sun exposure is inadequate in children
Helps reduce occurrence of symptoms of eczema/dermatitis when sun exposure is inadequate in children
Helps reduce occurrence of symptoms of eczema/dermatitis in children
Decrease/reduce/relieve skin scaling/crusty skin when sun exposure is inadequate in children
Decrease/reduce/relieve skin irritation when sun exposure is inadequate in children
Maintain/support skin health in children
Maintain/support skin health when sun exposure is inadequate in children
Enhance/improve/promote skin healing when sun exposure is inadequate in children
Maintain/support skin repair/healing/regeneration when sun exposure is inadequate in children

Indication Requirements

Product presentation must only refer to mild eczema.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.
Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).
Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder

Route of Administration Oral

Visual Identification

Active Ingredients

Bifidobacterium animalis ssp lactis 500 million CFU/g

colecalfiferol .0125 mg/g

Lactobacillus rhamnosus 5 billion CFU/g

Other Ingredients (Excipients)

Acacia

dl-alpha-tocopherol

maize starch

maltodextrin

medium chain triglycerides

silicon dioxide

sodium ascorbate

sucrose

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary